



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,728	10/23/2001	Toshio Kitamura	084335-0143	3800

7590 08/19/2004

Stephen B Maebius
Foley & Lardner
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/913,728	Applicant(s) KITAMURA ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 5/18/04. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-5,7-9,13-24 and 33-43.

Claim(s) withdrawn from consideration: _____.

Elizabeth C. Kemander

ELIZABETH KEMANDER
PRIMARY EXAMINER

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6/23/04.
10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s):

The objection to the specification under 35 U.S.C. 132 because it introduces new matter into the disclosure, as set forth at page 3 of the previous Office Action (18 November 2003) is withdrawn.

The rejection of claims 1c, 2-7, 9, 13-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter), as set forth at pages 3-4 of the previous Office Action (18 November 2003) is withdrawn.

The rejection of claims 7, 8, 23 and 24 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as set forth at page 5 of the previous Office Action (18 November 2003) is withdrawn in view of the amendment (23 June 2004).

The rejection of claim 8 under 35 U.S.C. 102(b) as being anticipated by Noguchi et al. (Blood 78:2548-2556, 1991, reference submitted by Applicant) as set forth at pages 4-5 of the previous Office Action (18 November 2003) is withdrawn in view of the amendment (23 June 2004).

The objection of claim 8, as set forth at page 11 of the previous Office Action (18 November 2003) is withdrawn in view of the amendment (23 June 2004).

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-5, 7-9, 13-24, 33-43 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The basis for this rejection is set forth at pages 5-7 of the previous Office Action (18 November 2003).

Applicants state that as the results of the examples reveal, the proximal region of Delta1 functions as a type I cytokine receptor superfamily, Delta1 has a specific and asserted utility. Applicants argue that according to the PTO's revised Interim Utility Guidelines Training Materials, methods for identifying compounds which bind to a specific receptor are not applicable to the general class of receptors and therefore, such an asserted utility must be considered specific for this reason alone. Applicants cite Utility Guidelines, Example 12, page 65, lines 1-6. Applicants argue that whether or not the as filed application supports TSLP ligand or IL-7 alpha receptor has no bearing on whether the claimed invention is supported by an asserted utility that is both specific and substantial. Applicants state that Delta1 has been identified in tissues such as heart, brain and lung but not in skeletal muscle and that the precise chromosomal location of Delta1 has been mapped. Applicants argue that the protein of the present invention is involved in signal transduction through JAK2 activation by forming a complex with heterologous receptors. Applicants assert that box 1 and box 2 regions of Delta1 are considered in the art to be important in intracellular signal transduction and box 1 is important for interaction of Jak and cytokine receptors. Applicants assert that JAK2 relates to leukemia and that JAK2 inhibitors are useful to treat such diseases as shown in the attached references. Applicants cite references listed on the submitted IDS. Applicants maintain that it is useful to screen for antagonists of Delta1 that activates JAK2.

Applicants' arguments have been fully considered but are not persuasive. Contrary to Applicants' assertion a utility must be specific AND substantial OR well-established. The specification fails to teach that the full length Delta1 protein has a defined biological activity. The specification only demonstrates that a chimera of EDER/Delta1 (transmembrane domain, and the box1 region of hEPOR was exchanged with the corresponding region of the Delta1) can activate JAK2 through the binding of EPO. Thus it is unclear how one would even screen for antagonists or agonists of Delta1, when the specification fails to disclose a ligand of Delta1 which activates JAK2. EPO is binding to the EPO receptor part of the chimera not Delta1. The instant invention is to Delta1. The asserted utility of screening is not specific. A tissue marker is not a utility which is specific to Delta1 because plenty of genes are expressed in heart, brain and lung, but not in skeletal muscle. Screening for drug candidates for immune system related diseases or possible treatments for cancer are not substantial utilities because the specification fails to teach a correlation between any disease and Delta1. Moreover, JAK2 is a kinase which associates with many receptors. The specification fails to teach that the interaction between Delta1 and JAK2 is involved in cancer.

Lastly, the Examiner stated that the specification as originally filed failed to provide support for TSLP ligand or IL-7 alpha receptor and a sequence comparison between Delta1 and IL-7 alpha receptor was needed because Applicants contended in the previous Office Action (18 November 2003) that the ligand of the protein of the invention is the thymic stromal lymphoprotein (TSLP), which facilitates B lymphopoiesis and stimulates thymocytes and mature T cells. The evidence as whole indicates that the rejection should be maintained.

Claims 1-5, 7-9, 13-24, 33-43 remain rejected under 35 U.S.C. 112, first paragraph, enablement. The basis for this rejection is set forth at pages 8-9 of the previous Office Action (18 November 2003). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicants' arguments have been fully considered but are not found to be persuasive for the reasons discussed above in the maintained rejection in 35 USC 101. Applicants state that the present version of the claims avoid the issues. This is not found persuasive as the claims are still drawn to claims to polynucleotides encoding Delta1 polypeptides modified to an unlimited extent relative to those exemplified. The specification is not enabling for these limitations. The evidence as whole indicates that the rejection should be maintained.

Claims 1-5, 7-9, 13-24, 33-43 remain rejected under 35 U.S.C. 112, first paragraph, written description. The basis for this rejection is set forth at pages 9-11 of the previous Office Action (18 November 2003). Applicants state that the present version of the claims are believed to avoid the concerns addressed in the Office action. This is not found persuasive as the claims are still drawn to claims to polynucleotides encoding Delta1 polypeptides modified to an unlimited extent relative to those exemplified. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The evidence as whole indicates that the rejection should be maintained.